

REMARKS

Claims 30-49 are pending in the application. Claims 30, 34, 39, 42, and 47 have been amended to better describe the invention and for consistency reasons. Favorable reconsideration in light of the amendments and the remarks which follow is respectfully requested.

The Amendments

The independent claims have been amended to better describe the direct positional relationship between the and the constituent. Support for the amendments exist in the specification, for example, at page 7, line 6 and page 8, lines 8-15.

Claims 34 and 42 have been amended to correct a spelling error. Support for the amendment exists in the specification, for example, at page 6, line 23.

The Enablement Rejection

Claims 30-49 have been rejected under 35 U.S.C. § 112, first paragraph, for enablement reasons with regard to native heparan sulfate and the transitional phrase. Referring to the arguments presented by the Applicants in the RCE Submission in June 2005, the Examiner asserts that the trace impurities of the native heparan sulfate are not disclosed or claimed. Applicants respectfully disagree.

Initially, it is noted that the RCE Submission of June 2005 states “[t]he native heparin sulfate materials contains trace impurities that come from other constituents of the outer layer of a red blood cell and/or mesothelial cell.” Thus, the subject “impurities” are indeed expressly covered by the claim language, which requires “a constituent of an outer layer of a blood cell, a constituent of an outer layer of a mesothelial cell”.

Moreover, Examples 1 and 3 expressly describe in a manner sufficient to teach one skilled in the art how to isolate such constituents. That is, the methods of preparing a “constituent” of the claims as described in the specification contains the subject impurity materials. As described by the specification, the preparation of constituents of the outer layer of a blood cell and/or constituents of the outer layer of a mesothelial cell

result in a final fraction that contains MULTIPLE constituents, some of which can include the subject "impurities".

Finally, as noted by MPEP § 2111.03, the transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931). MPEP § 2111.03 further notes *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) that clearly explains that "consisting of" functions to close the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.

The "constituent" of the claims is adequately described in the specification in a manner so that one skilled in the art can MAKE and USE the constituent, whether the constituent is big or small, so long as the constituent comes from the outer layer of a blood cell or the outer layer of a mesothelial cell.

The Adequate Description Rejection

Claims 30-49 have been rejected under 35 U.S.C. § 112, first paragraph, for not adequately describing the transitional phrase and heparan sulfate.

With regard to heparan sulfate, claims 34 and 42 have been amended to correct a spelling error, rendering the rejection for this aspect moot.

With regard to the transitional phrase, the Examiner asserts that the term "consists of" is not described in the specification. Applicants respectfully disagree. While the words "consists of" may not be present in the specification, this fact does NOT mean that the transitional phrase "consists of" cannot be used. The phrase "consists of" is a legal term that has inherent support in the word "containing" (numerous instances including page 3, line 32 in the specification). In other words, changing the transitional phrase from "comprising" to "consisting essentially of" or to "consists of" is a legal maneuver, and it is NOT necessary to have the words "consisting essentially of" or "consists of" in the specification to make such an amendment.

Furthermore, the general description of the hemocompatible surface in the specification provides support for a hemocompatible surface consisting of at least one

of an artificial compound, a natural organic compound, or an inorganic compound and a constituent of an outer layer of a blood cell, a constituent of an outer layer of a mesothelial cell or a combination thereof. Therefore, the specification as originally filed provides adequate support for the claims in their present form, and indicates that the inventors had possession of the invention at the time of filing.

The First Art Rejection

Claims 30-36, 38, 39, 41-47, and 49 have been rejected under 35 U.S.C. § 102(b) or § 103(a) over Baumann et al. Baumann et al relates to endothelial cell surface heparan sulfate (ESHS) bonded to oligoamide spacers which are in turn anchored to a synthetic polymer surface. The oligoamide spacer of Baumann et al has a 16-atom chain length for the cellulose surface and an 11-atom chain length for the silicon surface.

To establish anticipation, each and every claim feature must be disclosed in a single cited art document. The independent claims require a hemocompatible surface consisting of two elements: namely, 1) at least one of an artificial compound, a natural organic compound, or an inorganic compound and 2) a constituent of an outer layer of a blood cell, a constituent of an outer layer of a mesothelial cell or a combination thereof. Generally speaking, the first element is the surface while the second element renders the surface hemocompatible.

Baumann et al fails to disclose, teach, or suggest hemocompatible surfaces with only the two required elements. In particular, Baumann et al requires the presence of oligoamide spacers. The function of the “consisting of” transitional phrase is to EXCLUDE the use of oligoamide spacers in hemocompatible surfaces. Since Baumann et al does not disclose all of the claimed features, Baumann et al cannot anticipate any of the claims.

With regard to obviousness, the independent claims further stipulate the positioning of the constituent relative to at least one of an artificial compound, a natural organic compound, or an inorganic compound. Specifically, the claims require that the

constituent is firmly attached to the artificial compound, the natural organic compound, or the inorganic compound by at least one of chemical immobilization, photoimmobilization, adhesion, and drying. Baumann et al fails to teach or suggest that its ESHS is firmly attached to its synthetic polymer surface. Instead, Baumann et al teaches that its ESHS is attached to oligoamide spacers, and it is the oligoamide spacers which are attached to its synthetic polymer surface. This is important because attaching ESHS to oligoamide spacers, and then attaching oligoamide spacers to a synthetic polymer surface would NOT have suggested to one skilled in the art to firmly attach a constituent to the surface of an artificial compound, natural organic compound, or inorganic compound.

Furthermore, there are many disadvantages associated with using ESHS compared to using the hemocompatible constituents of the claimed invention. The preparation of ESHS requires the cultivation of endothelial cells and therefore ESHS can only be obtained in small quantities. Additionally, successful purification of ESHS is difficult to achieve. This is because the purification process is very time consuming, laborious, and cost intensive. Consequently, the combination of these factors makes ESHS coatings too expensive for commercially viable mass production. It is noted that solid phase synthesis or recombinant synthesis of ESHS is also not commercially useful as it is also too complicated and too expensive.

For these reasons, there are currently no products coated with ESHS available in the hemocompatible surfaces market. Therefore, ESHS is, at this time, merely an academic project and has made no significant contribution to technological progress in the field of hemocompatible surfaces.

Given the significant disadvantages of ESHS, those of skill in the art would not use ESHS as a hemocompatible coating and instead would choose to use the commercially viable synthetic heparin, since cultivation of endothelial cells and isolation of ESHS and purification of ESHS takes too much time, is too expensive, and results in too low yield which makes the ESHS not suitable for commercial use as coating material.

In contrast to Baumann et al, the claimed invention provides a significant step forward in technological progress in the field of hemocompatible surfaces. The claimed invention provides a fully hemocompatible surface that is not only simple to produce, but is also produced from source materials that are cheap and available in large quantities.

In light of the differences between the claims and Baumann et al, one skilled in the art would not have been motivated by Baumann et al to make the novel hemocompatible surfaces of the claims. And since Baumann et al does not teach or suggest hemocompatible surfaces consisting of two elements: namely, 1) at least one of an artificial compound, a natural organic compound, or an inorganic compound and 2) a constituent of an outer layer of a blood cell, a constituent of an outer layer of a mesothelial cell or a combination thereof, and since Baumann et al does not teach or suggest the relative positioning of these two elements, Baumann et al cannot render the claims obvious.

The Second Art Rejection

Claims 37, 40, and 48 have been rejected under 35 U.S.C. § 103(a) over Thompson in view of Baumann et al. Thompson relates to making a prosthesis that is made of metal, polymeric monofilaments or polymeric multifilament yarns. Thompson fails to teach or suggest hemocompatible surfaces consisting of two elements: namely, 1) at least one of an artificial compound, a natural organic compound, or an inorganic compound and 2) a constituent of an outer layer of a blood cell, a constituent of an outer layer of a mesothelial cell or a combination thereof. Thompson also fails to teach or suggest the relative positioning of these two elements.

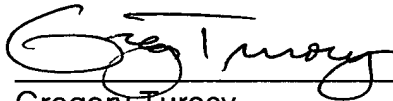
Claims 37, 40, and 48 are patentable because Thompson does not cure the deficiencies of Baumann et al with regard to the independent claims. Consequently, claims 37, 40, and 48 are patentable for the same reasons that claims 30, 39, and 47 are patentable.

Should the Examiner believe that a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

In the event any fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 50-1063.

Respectfully submitted,

AMIN & TUROCY, LLP

A handwritten signature in black ink, appearing to read 'Greg Turocy', is written over a horizontal line.

Gregory Turocy
Reg. No. 36,952

24th Floor, National City Center
1900 East 9th Street
Cleveland, Ohio 44114
(216) 696-8730
Fax (216) 696-8731